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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/547,207	08/26/2005	Paul Andrew Hamblin	V60033USw	4726

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EXAMINER
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NATARAJAN, MEERA

ART UNIT	PAPER NUMBER
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1643

NOTIFICATION DATE	DELIVERY MODE
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12/02/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/547,207	<b>Applicant(s)</b> HAMBLIN ET AL.	
	<b>Examiner</b> MEERA NATARAJAN	<b>Art Unit</b> 1643	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 August 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14, 16-18 and 21-26 is/are pending in the application.
- 4a) Of the above claim(s) 1-14 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16, 17 and 21-25 is/are rejected.
- 7) ☒ Claim(s) 26 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Applicant's amendments in the reply filed on 08/11/2008 is acknowledged and entered into the record.
2. Accordingly, Claims 1-14, 16-18, 21-26 are pending. Claims 1-14 and 18 are withdrawn as being drawn to non-elected inventions.
3. Claims 16, 17 and 21-26 will be examined on the merits.

### ***New Grounds of Rejection***

#### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 16, 17 and 21-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
6. The claims are broadly drawn to a method of treating a MUC-1 over-expressing epithelial cell tumors in a mammal, comprising administering to said mammal a nucleic acid molecule encoding a MUC-1 protein that raises an immune response to MUC-1 in said mammal in vivo, wherein the non-repeat region of the nucleic acid molecule has a

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RSCU value of at least 0.6 and has a level of nucleotide identity of less than 85% in comparison with the non-repeat region of SEQ ID NO:16.

7. Regarding the instant claim limitations, the specification does not appear to provide an adequate written description for all nucleic acid molecules having a "level of nucleotide identity of less than 85% in comparison with the non-repeat region of SEQ ID NO:16" because there is a lack of sufficient written description to support the claimed genus of nucleic acid molecules.

8. The standard for Written Description is met by "showing that an invention is complete by disclosure of sufficiently detailed, **relevant identifying characteristics ... i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure**, or some combination of such characteristics." See Enzo Biochem., Inc. v. Gen-Probe Incorporated 323 F.3d 956 (Fed. Cir. 2002).

9. There is no description of structural or functional features that identify the "non-repeat region" of a nucleic acid. The "non-repeat region" of SEQ ID NO:16 is not defined in the specification, therefore one of ordinary skill in the art would be unable to identify other nucleic acid molecules that have a "level of identity of less than 85% with the non-repeat region of SEQ ID NO:16". Without such critical identifying features, one skilled in the art would not be able to recognize other species/members of the genus of nucleic acid molecules.

10. Furthermore, the instant claims do not provide sufficient structural and functional characteristics coupled with a known or disclosed correlation between function and

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structure. A structural feature that would help identify the “non-repeat region” of a nucleic acid is lacking in the specification. The instant specification only provides the following statement for identifying non-repeat regions, “in the present invention, the non-repeat region of the codon-modified and the non-repeat region of optimal alignment of sequences for comparison may be conducted by the local identity algorithm of Smith and Waterman, by the identity alignment algorithm of Needleman and Wunsch, by the search for similarity methods of Pearson and Lipman, by computerized implementations of these algorithms, or by inspection”. This description is not adequate enough for one of ordinary skill in the art would to be able to identify nucleic acid molecules which teach the limitations claimed.

11. Therefore, the specification does not provide for sufficient written description to reasonably convey to one skilled in the relevant art that, at the time the application was filed, Applicant had possession of all nucleic acid molecules having a level of nucleotide identity of less than 85% in comparison with the non-repeat region of SEQ ID NO:16.

12. *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, makes clear that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116.) Consequently, Applicant was not in possession of the instant claimed invention. See *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398. Applicant is reminded that *Vas-Cath*

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makes clear that the written description provision of 35 U.S.C. § 112 is severable from its enablement provision. (See page 1115.)

***All other rejections are withdrawn in view of Applicants arguments in the reply filed on 08/11/2008.***

### ***Conclusion***

13. SEQ ID NOs: 13, 14, and 16 are free of the prior art.
14. Claims 16, 17 and 21-25 are rejected.
15. Claim 26 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MEERA NATARAJAN whose telephone number is (571)270-3058. The examiner can normally be reached on Monday-Thursday, 9:30AM-7:00PM, ALT. Friday. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MN

/Larry R. Helms/  
Supervisory Patent Examiner, Art Unit 1643